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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/508,821	05/26/00	ROULEAU G	2055MC/48747

HM12/0509
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EXAMINER	
GOLDBERG, J	
ART UNIT	PAPER NUMBER
1655	12

DATE MAILED: 05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/508,821	ROULEAU ET AL.	
	Examiner	Art Unit	
	Jeanine A Enewold Goldberg	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/1/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 9-11, drawn to a hGT1 gene, a method of prognosis of severity of schizophrenia by determining the CAG repeat of the hGT1 gene, and methods of categorizing psychiatric patients by the allelic variants of the CAG repeat.

Group II, claim(s) 6, drawn to a non-human mammal model.

Group III, claim(s) 7, 12, drawn to a method for screening of therapeutic agents for the prevention or treatment of schizophrenia using an non-human mammal.

Group IV, claim(s) 8, drawn to a method to identify genes part of or interacting with a biochemical pathway affected by the hGT1 gene.

3. As set out in 1.475, "An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories". The instant claims do not fall within one of these combinations of categories as set out in (d). Therefore, the method of using and the product have been considered one group.

A) Group I and Group II are directed to distinct products. The inventions of Groups I, II, are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The transgenic animal of Group II is a composition made up of structurally and functionally complex biological systems. Furthermore, the products of Groups I, II, can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, while transgenic animals can be used to express different proteins other than hGT1. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, are patentably distinct from each other.

B) Group I and (Group III and IV) are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I is for a method of prognosis of severity of schizophrenia by determining the CAG repeat of the hGT1 gene, and methods of categorizing psychiatric patients by the allelic variants of the CAG repeat. Alternatively, the method of Group III is for a method for screening of therapeutic agents for the prevention or treatment of schizophrenia using an non-human mammal. The method of Group IV is method to identify genes part of or interacting with a biochemical pathway affected by the hGT1 gene. The method of Group I relies upon nucleic acids where as the method of Group III relies upon the transgenic animal. The methods are further directed to

different objectives with different uses and method steps. Therefore the methods are distinct over one another.

C) Group II and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic animal of Group II may be used to produce proteins.

D) Group II and IV are patentable distinct inventions because the transgenic animal of Group II is not relied upon in the method of Group IV. Instead Group IV uses nucleic acids. Therefore, the inventions are novel and unobvious over one another.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because the literature searches required for examination of the groups identified above are not coextensive, restriction for examination purposes as indicated is proper.

5. A telephone call was made to JD Evans on April 13, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made. The examiner had indicated if no election had been made by April 20, 2001, the restriction would be sent in writing.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
May 4, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
5/7/01